Remarks

Upon entry of the foregoing amendments, claims 14-18 are pending. Claim 13 is cancelled without prejudice thereto or disclaimer thereof the subject matter contained therein. Claims 14-18 are sought to be amended without prejudice thereto or disclaimer thereof any subject matter omitted. The claim amendments place claim 14 into independent format, and the remaining claims dependent upon claim 14. Applicants believe that no new matter is introduced by these claim amendments, and their entry is respectfully requested.

Specification

The specification has been objected for failure to include sequence identification in the brief description of Figure 2. Office Action, page 2. This has been corrected by an amendment made above. Accordingly, Applicants request that the Examiner reconsider and withdraw this objection.

Claim Objections

Claims 13-18 are objected for reciting non-elected inventions. Office Action, pages 2-3. These objections are believed to be moot in light of Applicants' amendments. Claim 15 is also objected for allegedly "failing to further limit the subject matter of a previous claim." Applicants respectfully traverse this objection and point out that SEQ ID NO.: 6 is one species of the genus described by FPDV E2 protein. Accordingly, Applicants request that the Examiner reconsider and withdraw the objections.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 16 and 17 are rejected under 35 U.S.C. §112, first paragraph, for allegedly "failing to comply with the enablement requirement." Office Action, page 3. In particular, the Examiner asserts that "Pharmaceutical compositions and vaccines require evidence of a therapeutic benefit, and protection, respectively. The specification as filed does not appear to be enabled for either a composition conferring a therapeutic benefit or protection against pancreatic disease (FPDV) in fish." *Id.* In particular, the

Examiner asserts that Applicants have not given "any details about the challenge experiments." *Id.* at page 4, line 2. It appears that the enablement rejection is based upon the premise that without an explicit description of Applicants' experiments and data analysis, the skilled artisan would not know how to identify whether a given pharmaceutical composition or vaccine could actually confer a therapeutic or protective response upon challenge with FPDV. *See id.* at lines 7-14. Applicants respectfully disagree with the rejection.

The Examiner correctly recognized that Applicants describe successful experiments wherein the E2 protein was *actually* used as a pharmaceutical composition or a vaccine. In particular, the Examiner points to Applicants specification at page 17, lines 17-20 which states the following:

> A standardised challenge experiment performed at 8 weeks post-vaccination in Atlantic salmon fish showed that protection against challenge with salmon PD virus could be obtained with these recombinant sub-unit vaccines. In the experiment, lesions in pancreas, skeletal muscle and heart muscle were scored in ordinal [sic] way.[1]

The sentences immediately following this excerpt, however, point to the knowledge available to the skilled artisan at the time the captioned application was filed:

> The vaccine formulation comprising the E2 or E2-E3 proteins gave similar levels of protection *as obtained by the inactivated PD virus vaccine*, while vaccines containing the recombinant proteins resulting from the p130 and p98 constructs respectively were less protective . . . [than the inactivated] PD virus vaccine.[2]

See page 17, lines 22-25 (emphasis added). Hence, the state of the art at the time that Applicants filed their application included experimental tests and analytical methods to enable the determination of whether a given pharmaceutical composition or vaccine was effective against FPD virus.

Such experimental and analytical methods are provided in EP 0712926 A2 (hereafter, "the '926 application," provided herewith as Exhibit A). The '926 application

[1] Applicants note that "ordinal" is an obvious typographical error that has already been corrected to "ordinary" in a Preliminary Amendment filed February 26, 2004, pages 8-9.
[2] Applicants note that their conclusions regarding the protection conferred by their claimed vaccine *is* backed by evidence. As explained in the discussion that follows, the data giving rise to Applicants' conclusions need not be provided to enable the claims.

was published on May 22, 1996, prior to the captioned application. This application is referenced at page 1, line 27 to page 2, line 10 of the captioned application.

The table on page 15 of the '926 application unambiguously shows that the group of fish vaccinated with the formalin-inactivated PD virus (group B) is protected against challenge with PD virus. The vaccination protocol is provided at page 14, lines 1-7; and negative and positive vaccination controls are described at page 14, lines 9-23, and in the table on page 15. Moreover, methods of histological and viral scoring are also described in this table. In particular, this table in the '926 application describes that histological observations for the presence of lesions in a subject's pancreas or heart at 10, 14 or 21 days post vaccination are observed to assist in the analysis of a vaccine's efficacy. Moreover, the '926 application describes that "[b]lood samples for antibody tests, kidney and heart tissue samples for virus isolation, and pyloric caeca, heart and muscle samples for histology were taken." Page 14, lines 22-23. The figures of the '926 application also identify the appearance of FPDV caused lesions. *See* page 5, lines 21-46, and corresponding figures. Hence, the '926 application demonstrates that at the time the captioned application was filed, the skilled artisan would know how to evaluate and identify whether a given pharmaceutical composition or vaccine could actually confer a therapeutic or protective response upon challenge with FPDV.[3]

Relying upon judicial precedent, the M.P.E.P. explicitly states the following:

> The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).
>
> The state of the art existing at the filing date of the application is used to determine whether a particular disclosure is enabling as of the filing date. >*Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004) . . . .

[3] Applicants note, however, that the specific identification of the E2 protein for use in an FPDV vaccine was not described prior to Applicants' present patent application.

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M.P.E.P. 8th ed., §2164.05(a) (Oct rev. 2005). Hence, techniques need not be explicitly described if they are well known to the skilled artisan.

Here, the experimental and analytical evaluative *techniques* Applicants used to identify the efficacy of a pharmaceutical composition or vaccine are well known to the skilled artisan.[4] Indeed, Applicants have stated that they have employed a standardized challenge model and scored results in the ordinary way. Moreover, Applicants have even provided the statistical analysis that can be used to evaluate raw data: "Significant levels were calculated from Kruskal-Wallis one-way analysis of variance (non-parametric test)." *See* page 17, lines 21-22. Thus, one of skill in the art will be able to determine whether the claimed composition will confer a therapeutic response or a protective response upon challenge with FPDV. Therefore, Applicants' specification does enable the claims. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the enablement rejection.

Conclusion

Applicants do not believe that any other fee is due in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. 02-2334. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. 02-2334.

[4] See footnote 3.

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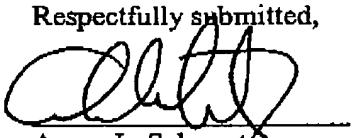
Applicants submit that this application is in condition for allowance, and request that it be allowed. The Examiner is requested to call the Undersigned if any issues arise that can be addressed over the phone to expedite examination of this application.

Respectfully submitted,



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